

## **II. REMARKS**

As an initial matter, I gratefully acknowledge the telephone conference conducted with Examiner Rodriquez (571-272-7070) on May 30, 2007, wherein the Examiner confirmed that the Office Action of March 8, 2007 is a non-final Office Action.

By the present amendment, claims 28-30 have been canceled without prejudice. Independent claims 21, 31, 36 and 37 have been amended to incorporate the subject matter of dependent claims 28-30. Thus, independent claim 21 has the same scope as previous claim 28.

The present amendment adds no new matter to the above-captioned application.

### **A. The Invention**

The present invention pertains broadly to a method for dispensing a substance into a mouth, such as could be used to dispense a breath freshener, a flavoring agent, a medication, or a combination of these substances. In one embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 21. In another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 31. In yet another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 36. In still another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 37.

Various other embodiments, in accordance with the present invention, are recited in the dependent claims. All of the embodiments, in accordance with the present invention, provide the advantage of using a "mouth and tongue stud" to dispense a substance into a wearer's mouth.

**B. The Rejection**

Claims 21-31, 36 and 37 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Denney et al. (U.S. Patent 6,047,209, hereafter, the "Denney Patent") in view of Edwards (U.S. Patent 4,943,274).

Applicant respectfully traverses the rejection and requests reconsideration of the application for the following reasons.

**C. Applicant's Arguments**

A *prima facie* case of obviousness requires a showing that the scope and content of the prior art teaches each and every element of the claimed invention, and that the prior art provides some teaching, suggestion or motivation to combine the references to produce the claimed invention. *In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992); *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Thus, a proper rejection under Section 103 also requires showing (1) that the prior art would have suggested to a person of ordinary skill in the art that they should make the claimed device or carry out the claimed process, (2) that the prior art would have revealed to a person of ordinary skill in the art that in so making or doing, there would have been a reasonable expectation of success, and (3) both the suggestion and the reasonable expectation of success must be found in the prior art and not in the applicants' disclosure. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). An obviousness analysis, however, is not a rigid formulaic analysis, but is a flexible determination grounded in the facts of the case. *KSR International Co. v. Teleflex Inc.*, 127 St. Ct. 1727, 1739 (2007). Indeed, the common sense of those skilled in the art may demonstrate why some combinations are obvious and others are not. *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007).

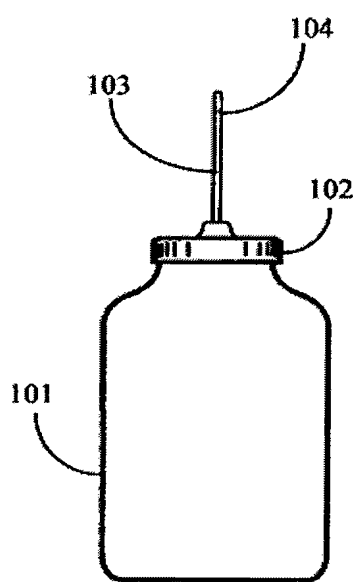
In the present case, the Examiner has failed to establish a *prima facie* case of obviousness against the presently claimed invention because neither the Denney Patent nor the Edwards Patent teaches, or even suggests, "the substance is dispensed into the wearer's mouth by dissolving the

substance over time in the wearer's saliva" as recited by independent claims 21, 31, 36 and 37.

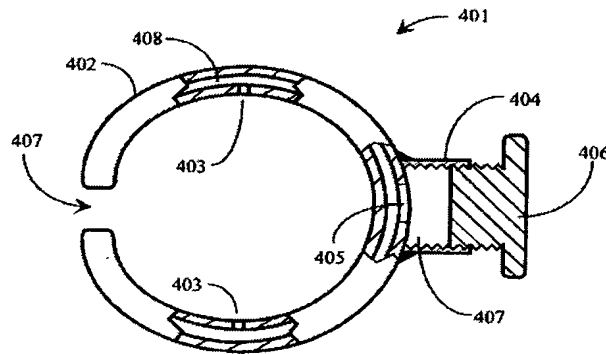
The Examiner's Section 103 rejection is also untenable and must be withdrawn because the combination of the Denny Patent and the Edwards Patent fails to teach, or even suggest, a "method for dispensing a substance into a mouth" that includes the step of "providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud... wherein the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar" and wherein "the first end member removably attaches to the one end of the bar" and "mounting the bar of the stud in a fistula..." as recited in independent claims 21, 31, 36 and 37.

#### i. **The Denny Patent**

U.S. Patent 6,047,209, the Denny Patent, discloses a "method and apparatus for maintenance of pierced orifices" for injecting fluid into a pierced body orifice (See Abstract). Specifically, the Denny Patent discloses a "needle" (103) as shown in Figure 3, or a "ring" (401) as shown in Figure 4. Both of these Figures are reproduced below.



**Fig. 1**



**Fig. 4**

Neither the apparatus of Figure 1 nor of Figure 4 is a “mouth and tongue stud” because neither needle (103) nor ring (401) includes structure that would allow them to remain in the tongue or other piercing that involves the mouth. Therefore, the Examiner’s Section 103 rejection is facially flawed because the Denny Patent does not teach, or even suggest, (1) “providing a mouth and tongue stud including means for dispensing a substance...” as recited in independent claims 21, 31, 36 and 37 of the present application. Furthermore, the Denny Patent does not teach, or suggest, (2) “mounting the bar of the stud in a fistula...” and (3) “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as recited in independent claims 21, 31, 36 and 37.

Those skilled in the art would realize that the mouth is a very active place so jewelry used in the mouth must have appropriate structure for securing it in place; otherwise, the jewelry will fall out of place and be swallowed or aspirated. The production of saliva, which is a lubricant, makes this problem even more acute. A reasonable person skilled in the art would not place a needle (103), or an unsecurable ring (401), in the mouth of a wearer to maintain a “pierced orifice” because of the hazard created by placing unsecurable objects in the mouth. In other words, the fact that the needle (103) and the ring (401) disclosed by the Denny Patent do not have structure to secure them in place in a fistula is evidence that these devices are not a “mouth and tongue stud” as recited by the independent claims.

In addition, the Denny Patent describes placing the needle (103) in a “pierced orifice” having an interior (302), but the use of hydrogen peroxide, soap and water, and topical antibiotics would reasonably suggest to one skilled in the art that Denny discloses a device for application to “any pierced orifice on the body” (col. 3, lines 28-54, and Figure 3), which would not include piercings involving the mouth. There is nothing in the Denny Patent that teaches, or even suggests, that the method would apply to intraoral piercings, and the common sense of a person of ordinary skill in the art would lead one away from using any of the devices disclosed by Denny in that manner.

However, these are not the only deficiencies in the teachings of the Denny Patent demonstrating that Denny does not teach a “mouth and tongue stud” as recited in the claims. The Denny Patent also does not teach, or suggest, that (a) “the stud comprises a bar having ends, a first end

member attached to one end of the bar and a second end member attached to an other end of the bar” and (b) “the first end member removably attaches to the one end of the bar” as recited in independent claims 21, 31, 36 and 36.

As shown in Figure 1 of the Denny Patent, the needle (103) has no “first end member” and no “second end member” as recited in claims 21, 31, 36 and 37. This fact is even more evident from Figure 3 of the Denny Patent, which is reproduced below.

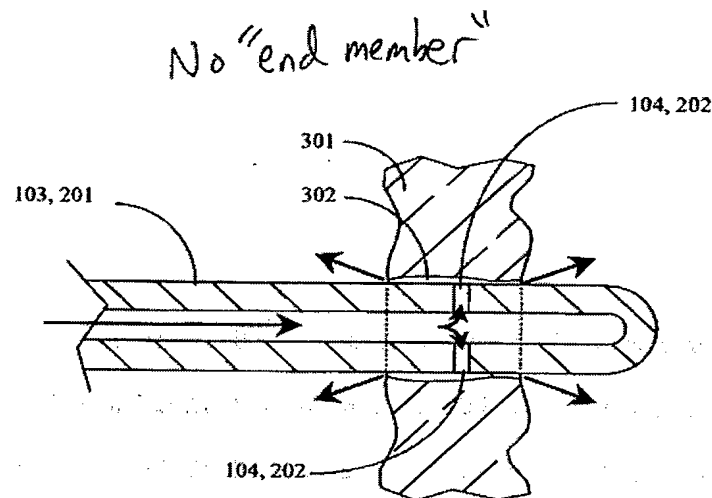


Figure 3 (modified) of the Denny Patent

I have pointed out and clearly shown that the Denny Patent does not teach, or even suggest, devices that are mouth and tongue studs, or that could even be reasonably used in the oral cavity of a wearer. Therefore, the Denney Patent cannot teach, or even suggest, the subject matter of claims 21, 31, 36 and 37 because the reference does not disclose the step of “providing a mouth and tongue stud including a means for dispensing a substance.”

#### **Examiner Improperly Mixes Up Components of Different Denny Devices**

The Federal Circuit has ruled that the United States Patent and Trademark Office (USPTO) must give a fair reading to what a reference teaches as a whole. *In re Gordon*, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). In the present case, the Examiner has not given a fair reading to the subject matter the Denny Patent teaches as a whole. The Denny Patent plainly discloses a device that includes either a

needle (103) or a ring (401), neither of which a person of ordinary skill in the art would reasonably construe to be a “mouth and tongue stud.” Needle (103) and ring (401) are two separate and distinct embodiments of Denny’s invention, yet the Examiner persists in incorrectly referring to these different embodiments as if their parts are interchangeable, which they are not (Office Action, dated March 8, 2007, at 2, lines 11-22; Office Action, dated June 14, 2006, at 2, lines 13, to at 3, line 4; and Office Action, dated March 2, 2006, at 3, lines 7-15).

For example, the Examiner states “[t]he method comprises the steps of: (a) providing a mouth and tongue stud (103, 201)...(Abstract)” (Office Action, dated March 8, 2007, at 2, lines 14-16). However, a person of ordinary skill in the art would instantly realize that the structures (103) and (201) are needles (See col. 3, lines 45-47; col. 4, lines 14-17; and Figures 1 and 2). A person of ordinary skill in the art would immediately know that needles (103) and (201) are not a “mouth and tongue stud” as the Examiner maintains.

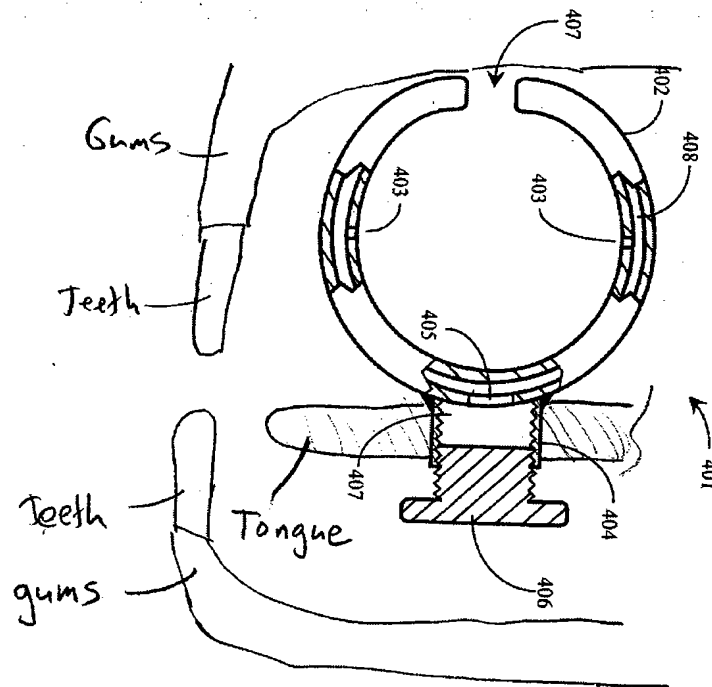
The Examiner then states that “[t]he stud comprises a bar (404) having ends (Figs. 4 and 5)” (Office Action, dated March 8, 2007, at 2, line 19). A person of ordinary skill in the art would instantly realize that base (404), shown in Figures 4 and 5, is not an element of the needles (103) and (201) as the Examiner contends. Therefore, the Examiner has grossly misconstrued the teachings of the Denny Patent. I have repeatedly asked the Examiner to explain how a person of ordinary skill in the art would reasonably have been motivated to mix and match these needles (103) or (201) with the base (404) when these structures pertain to substantially different devices (See Amendment (E), filed October 19, 2006, at 10, lines 9-12; and Amendment (D), filed May 31, 2006, at 11, lines 3-19). The Examiner has not provided a reasonable explanation for mixing up the components of Denny’s different devices because she cannot. A person of ordinary skill in the art would not mix up the components of Denny’s different embodiments as the Examiner has done.

#### **An Absurd Result**

If one where, for the sake of argument, to construe base (404) of the embodiment shown in

Figure 4 as a “bar having ends” of a “mouth and tongue stud” as the Examiner contends (Office Action, dated March 8, 2007, at 2, lines 14-21), the sketch of modified Figure 4 provided below makes it crystal clear how flawed such an interpretation would be. There is absolutely no teaching, suggestion, motivation, or hint, in the disclosure of Denny that would lead a person of ordinary skill in the art to use the device of Figure 4 in the manner that the Examiner contends is disclosed or obvious. Simply put, a person of ordinary skill in the art would not mount the base (404) in the fistula of a tongue or lip as the Examiner contends because of the damage the rigid ring (402) having two prongs would do in the wearer’s mouth. The Examiner’s suggested use of Denny’s device is contrary to the common sense and conventional wisdom regarding how a “mouth and tongue stud” is constructed and worn.

In addition, a person of ordinary skill in the art would immediately realize that the base (404) of Denny’s ring (401) is not a “bar having ends” of a “mouth and tongue stud” because a “bar” of a “mouth and tongue stud” is used to mount the stud to the wearer by “mounting the bar of the stud in a fistula in a wearer’s tongue or in the wearer’s lip.” As shown in Figures 4 and 5 of the Denny Patent,



Modified Figure 4 of Denny

the base (404) is a short structure. A person of ordinary skill in the art would immediately realize that such a short structure could not be used as the “bar” of a “mouth and tongue stud” because the “bar” must be sufficiently long; otherwise, the “stud” will become embedded in the tongue or lip of the wearer which is an undesirable complication of “mouth and tongue stud” use (See 43 AUSTRALIAN DENTAL JOURNAL 387, 388 (1998)(of record)).

A person of ordinary skill in the art would also instantly realize that the base (404) disclosed by the Denny Patent is too short and fat for use as the “bar” of a “mouth and tongue stud.” Based on a conventional length of 12-15 mm for the bar of a tongue barbell, for example, if the base (404) were made this length, it would also have a width that is about the same (See Figure 4 of the Denny Patent, and 43 AUSTRALIAN DENTAL JOURNAL at 388). This would be an exceptionally wide “bar.” In addition, the ring body (402) would be about four times larger as shown by Figure 4 of Denny, or about 48-60 mm, which is way too large a structure for use in a wearer’s mouth.

**The Device of Figure 4 is a Ring not a Stud**

A person of ordinary skill in the art would also appreciate that the device shown in Figure 4 is a “ring” and not a “stud.” A “stud” is a “small knob, nail head, rivet, or the like fixed in and slightly protruding from a surface,” (See THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1278 (1979), filed herewith), such as the non-limiting device shown in Figure 11 of the above-captioned application. A “ring,” on the other hand, is a “circular object...with a vacant center” (See THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1119 (1979), filed herewith). Denny’s Figure 4 plainly discloses a ring and not a stud.

For all of the above reasons, the Examiner’s contention that Denny discloses a “tongue and mouth stud” is flawed because the Denny Patent does not teach, or suggest, that the base (404) is used to mount the ring (401) to a pierced tongue or lip. On the contrary, the Denny Patent explicitly teaches that it is the ring body (402), and not the base (404), that is placed through the orifice of a piercing (col. 4, lines 59-66). In addition, the common sense of a person of ordinary skill in the art dictates that the



devices disclosed by Denny are not employed intraorally, due to the two prongs of ring (402), in the manner that the Examiner contends. In sum, the Denny Patent does not teach, or even suggest, “mounting the bar of the stud in a fistula in a wearer’s tongue or in the wearer’s lip” as recited in independent claims 21, 31, 36 and 37.

**Denny does not Disclose Using Saliva to Dispense a Substance**

The Denny Patent also does not teach, or suggest, that “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as recited by claims 21, 31, 36 and 37. As admitted by the Examiner, the Denny Patent discloses that the substance is disposed “by injecting the substance into the piercing” (Office Action, dated March 8, 2007, at 4, lines 11-12; Office Action, June 14, 2006, at 4, lines 21-23). In fact, the Examiner admits that the Denny Patent “fails to disclose that the substance is disposed by dissolving the substance over time in the wearer’s saliva” (Office Action, dated March 8, 2007, at 3, lines 12-13).

Despite these admissions, the Examiner contends that it would have been obvious for the substance, after it has been injected into the piercing, to also dissolve over time in the wearer’s saliva once in the mouth and that such a condition would meet the claimed limitation (Office Action, dated March 8, 2007, at 4, lines 13-18; and Office Action, dated June 14, 2006, at 4, line 22, to at 5, line 3). I disagree with the Examiner’s conclusion because the Examiner has misread the claim and the teachings of the Denny Patent.

According to claims 21, 31, 36 and 37, the “substance is dispensed into the wearer’s mouth by dissolving the substance...in the wearer’s saliva.” In other words, the “substance,” in accordance with the claimed invention, is dispensed into the mouth by dissolving it in the wearer’s saliva. On the other hand, as the Examiner concedes, the Denny Patent explicitly discloses that its apparatus is “for injecting fluid into a pierced body orifice” (See Abstract, emphasis added). The Examiner states, without any factual support, that

“it would have been obvious to one having ordinary skill in the art...to have the substance after being injected into the piercing also being dissolved over time in the wearer’s

saliva since the substance will not be dissolved immediately by the wearer's saliva in the mouth but rather it will take an amount of time for the substance to be completely dissolved" (Office Action, dated March 8, 2007, at 4, lines 13-18)(emphasis added).

The Examiner contends that after the substance has been injected from Denny's device into the wearer's mouth that it would be obvious for the substance to be further dissolved by the wearer's saliva.

I do not agree with the Examiner's contention, however, the issue is not germane to the claimed invention. The claimed invention recites that "the substance is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva." Thus, in accordance with the claimed invention, the (a) "substance" is (b) "dispensed into the wearer's mouth" by (c) "dissolving the substance over time in the wearer's saliva." According to the claimed invention, the substance is dispensed into the wearer's mouth by dissolving it in the wearer's saliva. Dissolving of the substance by saliva is the manner in which the substance is dispensed into the wearer's mouth. The substance gets into the mouth because it is dissolved by the wearer's saliva.

According to the Examiner, Denny discloses injecting the substance into the subject's mouth. No saliva is involved to get the substance into a subject's mouth. It is irrelevant, with respect to the claimed invention, whether the substance is further dissolved while in the subject's mouth after the substance is in the mouth. Therefore, it is irrelevant to the claimed invention whether the substance, after being injected into the mouth by Denny's device, is subsequently further dissolved over time in saliva. The presently claimed invention recites using saliva to dissolve the substance so as to dispense the substance into the wearer's mouth, which means that the substance is dissolved by saliva before or simultaneously with dispensing.

A person of ordinary skill in the art would instantly appreciate that the claimed invention passively dispenses the substance into the mouth by dissolving it using the wearer's saliva. A person of ordinary skill in the art would also instantly appreciate that Denny discloses actively dispensing a substance by injection. A person of ordinary skill in the art, realizing that the claimed invention pertains to passive dispensing of the substance into the mouth using saliva, would understand that it is distinguished from Denny's active injection process.

For all of the above reasons, the Denny Patent does not teach, or suggest, the substance “is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as recited by independent claims 21, 31, 36 and 37.

#### **Summation of the Deficiencies of the Denny Patent**

In sum, the Denny Patent does not teach, or even suggest, a “mouth and tongue stud” as recited in independent claims 21, 31, 36 and 37. Furthermore, the Denny Patent does not teach, or even suggest, “mounting the bar of the stud in a fistula formed in a wearer’s tongue or in the wearer’s lip” as recited by independent claims 21 and 31 and, “mounting the bar of the stud in a fistula in a part of wearer’s mouth” as recited by independent claims 36 and 37 of the present application. The Denny Patent also does not teach, or suggest, that “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as recited by independent claims 21, 31, 36 and 37 of the above-captioned application.

As admitted by the Examiner, the Denny Patent also does not teach, or suggest,

“a bar having ends, a first end member attached to one end of the bar and a second end member attached to another end of the bar where the first end member is removeably attached to one end of the bar and mounting the stud in the fistula comprises mounting the bar of the stud in the fistula” (Office Action, dated March 8, 2007, at 2, line 22, to at 3, line 3).

#### **ii. The Edwards Patent**

The Edwards Patent discloses an “apparatus for applying earlobe medicine” which is inserted into the earlobe (See Abstract). This ear apparatus is not a mouth and tongue stud and there is no teaching, or suggestion, that the apparatus would be used in the oral cavity. One skilled in the art would recognize that the apparatus (10) as shown in Figures 1 and 2 does not have the features of a mouth and tongue stud and is not suitable for use in the mouth. Specifically, apparatus (10) has a relatively pointed protruding “end” (54). Mouth and tongue studs do not have points such as “end” (54) because such a pointed structure would seriously damage the mucosal surfaces in the mouth.

In addition, apparatus (10) has a felt pad (50) as a backing for retainer (52). Mouth and tongue

studs, unlike earrings and devices for inserting into the earlobe, are restricted to certain non-toxic suitable materials for putting into the mouth. Felt is not a suitable material for the mouth. In the wet environment of the mouth, the felt would quickly degrade, break apart, and present an aspiration hazard. Furthermore, retainer (52) as shown in Figure 2 is only held in place by friction. Mouth and tongue studs cannot use simple friction retainers because the connection between the retainer and the rest of the apparatus is not robust. The mouth is a very active place with eating, drinking, speaking, and facial expressions going on. As a result, mouth and tongue studs must be securely inserted into the tongue or lip. In addition, if a mouth and tongue stud falls out into the mouth there is a serious potential for harm from aspirating the stud or its component parts into the lungs. Generally, a threaded connection, or a weld, and the like, is used to attach an "end member" of the mouth and tongue stud to the bar because this is a suitably secure connection. Friction retainers or clasps are not used.

Lastly, the apparatus (10) disclosed by Edwards has a resilient housing (16) made of neoprene, polypropylene or polyethylene so that housing (16) is squeezable (col. 2, lines 15-25, and col. 3, lines 3-10). Such a squeezable housing is unsuitable for use on the mouth and tongue stud for several reasons. First, housing (16), being compressible, would defeat one of the purposes of a mouth and tongue stud, being to enhance sexual activity. Second, the housing (16) could not hold the "antibiotic gel, petroleum or aloe-based ointments" (col. 2, lines 22-24) effectively because, once the apparatus (10) was inside the mouth, the housing would be compressed by some portion of the mouth. Thus, once in the mouth, housing (16) would not be an effective reservoir.

Therefore, given the fact that the apparatus disclosed by Edwards has a different structure from the present invention, is not a mouth and tongue stud, and can not function as a mouth and tongue stud, it is clear that any rejection under 35 U.S.C. §§ 102(b) and 103(a) relying upon the Edwards reference would be untenable.

### **iii. Summary of the Disclosures**

The Denny Patent discloses needles attached to a bottle, or a ring (401) with a base (404)

disposed in the middle of the ring body (402). The Denny Patent does not teach, or suggest, a “mouth and tongue stud” in accordance with the presently claimed invention. The Denny Patent also does not teach, or suggest, employing either the needle or the ring devices intraorally. Therefore, the Denny Patent cannot teach, or suggest, “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva.”

The Edwards Patent discloses an apparatus for applying earlobe medicine. It does not teach, or suggest, a “mouth and tongue stud” and it does not teach, or suggest, employing its apparatus in the mouth of a wearer.

In view of the above, the combination of the Denny Patent and the Edwards Patent cannot teach, or suggest, a “mouth and tongue stud” as recited in the present claims especially because neither the Denny Patent nor the Edwards Patent teach, or suggest, a “mouth and tongue stud.” Furthermore, the combination of the Denny Patent and the Edwards Patent cannot teach, or suggest, a device suitable for intraoral use. Consequently the combination of the Denny Patent and the Edwards Patent does not teach, or suggest, “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as recited by independent claims 21, 31, 36 and 37.

The combination of the Denny Patent and the Edwards Patent also does not teach, or suggest, “providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud... wherein the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar” and wherein “the first end member removably attaches to the one end of the bar” and “mounting the bar of the stud in a fistula...” as recited in independent claims 21, 31, 36 and 37.

For all of the above reasons, the Examiner has failed to establish a prima facie case of obviousness against the invention recited by independent claims 21, 31, 26 and 37.

#### **iv. No Proper Motivation to Combine the Denny and Edwards Patents**

The Examiner has also failed to establish a proper teaching, motivation or suggestion to

combine the Denny and Edwards Patents. See In re Rouffet, 47 U.S.P.Q.2d 1453, 1456 (Fed. Cir. 1998). Furthermore, the common sense of those skilled in the art may demonstrate why some combinations are obvious and others are not. Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1161 (Fed. Cir. 2007). In this case, the Examiner contends that it would be obvious that

“the bar and second end member of the stud of Edwards can be applied to the stud disclosed by Denny such that the first end member (501) is connected to one end of the bar of Edwards in such a way that the bar of the modified stud is mounted in a fistula formed in a wearer’s tongue or in the wearer’s lip as disclosed by Denny...” (Office Action, dated March 8, 2007, at 3, lines 10-16).

I object to the Examiner’s contention on multiple grounds. First, as discussed above, Denny discloses a “ring” and not a “stud.” Second, Denny does not disclose mounting a “stud” or a “ring” in a fistula in a wearer’s mouth or lip as discussed above. Third, the conduit (30) and the felt pad (50) disclosed by Edwards are not suitable structures for intraoral use. Specifically, “mouth and tongue studs” cannot be constructed to have points such as “end” (54) of Edwards’ conduit (30) disposed intraorally because such a pointed structure would seriously damage the mucosal surfaces in the mouth.

In addition, Edwards discloses the felt pad (50) is a backing for retainer (52). Mouth and tongue studs, unlike earrings and devices for inserting into the earlobe, are restricted to certain non-toxic suitable materials for putting into the mouth. Felt is not a suitable material for use in the mouth. In the wet environment of the mouth, the felt would quickly degrade, break apart, and present an aspiration hazard. Furthermore, retainer (52) as shown in Figure 2 is only held in place by friction. Mouth and tongue studs cannot use simple friction retainers because the connection between the retainer and the rest of the apparatus is not robust. The mouth is a very active place with eating, drinking, speaking, and facial expressions going on. A person of ordinary skill in the art would know that if a mouth and tongue stud falls out into the mouth of the wearer, then there is a serious potential for harm from aspirating the stud or its component parts into the lungs. As a result, mouth and tongue studs must be securely inserted into the tongue or lip, but Edwards’ felt pad (50) cannot provide a sufficiently secure attachment. Generally, only more secure connections, such as a threaded connection, a weld, or an equivalently secure connection, is used to attach an “end member” of the mouth and tongue stud to the

bar. Friction retainers or clasps, such as disclosed by Edwards, are not used.

In sum, the proposed application of Edwards' conduit (30) and felt pad (50) to Denny's device (401) is not properly motivated because Edwards' conduit (30) and felt pad (30) connection is unsuitable for intraoral use. Thus, the proposed combination of Edwards and Denny is contrary to the common sense and experience of those of ordinary skill in the art, and is, therefore, not properly made.

The Federal Circuit has also ruled that a proposed modification of a prior art device that obliterates an essential feature of the prior art device is not obvious. McGinley v. Franklin Sports, Inc., 60 U.S.P.Q.2d 1001, 1110-11 (Fed. Cir. 2001). In this case, the Examiner proposes to modify the "ring" device (401) "in such a manner" that the base (501) includes the conduit (30) and felt pad (50) of Edwards so that the base (501) would be mounted in the fistula in place of the ring body (402), (Office Action, dated March 8, 2007, at 3, lines 10-16). In other words, the Examiner's proposed modification is to substantially change Denny's "ring," a device mounted by a ring-shaped body (402), into a "stud" (i.e., in this case, a device mounted by base (501) or by some modified version of base (501)). However, this proposed modification is either impermissible or nonobvious because it would completely change the character and nature of Denny's device (i.e., changing it from a "ring" to a "stud"), thereby obliterating the essential ring-mounted character of the device. Furthermore, the Examiner's proposed combination would result in a variation of the absurd result illustrated in the modified Figure 4 of Denny, shown above. This absurd result, which is contrary to the common sense of those skilled in the art, is both an impermissible combination and nonobvious.

I further object to the Examiner's proposed combination of the Denny Patent and the Edwards Patent on the grounds that a person of ordinary skill in the art would have no clue how to construct or use the device asserted by the Examiner. I respectfully request that the Examiner provide a sketch or drawing illustrating how she believes the Denny device would be modified by the teachings of the Edwards Patent.

For all of the above reasons, the Examiner has failed to establish a prima facie case of obviousness against independent claims 21, 31, 36 and 37.

**v. Claims 21-27**

With respect to claims 21-27, the Examiner admits that the Denny Patent does not teach, or suggest, that “the substance comprises a breath freshener or a flavoring agent or a breath freshener mixed with a flavoring agent” (Office Action, dated March 8, 2007, at 4, lines 1-3; Office Action, dated June 14, 2006, at 4, lines 11-13; and Office Action, dated March 2, 2006, at 4, lines 6-8). However, the Examiner contends, without any factual basis, that it would be obvious for the substance to comprise “a breath freshener or flavoring agent or a breath freshener with a flavoring agent or a medication mixed with a breath freshener or a medicine with a flavoring agent since the medication will have a flavor to it whether the flavor pleasantly appeals to user or not it still has a flavor to it and as for the breath freshener, the antibiotic medication will kill also the bacteria that causes bad breath and therefore work as a breath freshener” (Office Action, dated March 8, 2007, at 4, lines 4-10; Office Action, dated June 14, 2006, at 4, 14-20).

**A Medication is not a Flavoring Agent**

The Examiner’s contention is flawed on multiple grounds. First, during examination, the claims should be given their broadest reasonable interpretation consistent with the specification, *In re Hyatt*, 54 U.S.P.Q.2d 1664, 1667 (Fed. Cir. 2000); however, this does not give the Examiner license to give an unreasonable interpretation to the claims. In this case, a person of ordinary skill in the art would understand from my original specification, at 6, lines 12-13, that a “flavoring agent” is something that improves the taste of the substance. It is unreasonable for the Examiner to construe the term “flavoring agent” to include simply anything that has a “flavor,” including bad tasting medications.

**Antibiotics are not “Breath Fresheners”**

Second, the Examiner’s contention that an “antibiotic medication will kill also the bacteria that causes bad breath and therefore work as a breath freshener” is flawed because the Examiner has not



provided any evidence in support of this position. I remind the Examiner of her obligation under the Administrative Procedure Act to show the evidence on which her findings are based. In re Lee, 61 U.S.P.Q.2d 1430, 1433 (Fed. Cir. 2002). The Examiner cannot simply speculate or misread what the prior art teaches; instead, the Examiner must provide “substantial evidence support” for any Section 103 rejection. In re Zurko, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001). In this case, not only has the Examiner failed to provide “substantial evidence support” for the contention that antibiotics are “breath fresheners” because they kill bacteria, I previously provided evidence to refute the Examiner’s position. The Examiner has improperly ignored this evidence.

In particular, the record reflects two medical articles pertaining to halitosis (i.e., bad breath), namely, 12 CLINICAL EVIDENCE CONCISE 367, 367-8 (2004) and 15 CLINICAL EVIDENCE CONCISE 472-3 (2006), which were previously filed and discuss effective treatments used for physiological halitosis. Antibiotics are not listed as an effective treatment for physiological halitosis.

On the other hand, the Examiner contends, without any factual support, that antibiotics do treat bad breath, and are therefore “breath fresheners.” In view of two medical articles discussed above, I respectfully traverse any “Official Notice” the Examiner is making regarding antibiotics being “breath fresheners.” The Examiner now must produce “substantial evidence support” for the proposition that antibiotics are “breath fresheners” (i.e., effectively kill bacteria and treat bad breath), or withdraw the Section 103 rejection standing against claims 21-27.

For all of the above reasons, the Examiner has not established a prima facie case of obviousness, against the subject matter of claims 21-27.

### **III. CONCLUSION**

The Examiner has failed to establish a prima facie case of obviousness against independent claims 21, 31, 36 and 37 of the above-captioned application because neither the Denny Patent nor the Edwards Patent teach, or even suggest, (i) a “mouth and tongue stud” and (ii) “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as

recited in the independent claims. The combination of the Denny Patent and the Edwards Patent also does not teach, or suggest, the step of “providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud... wherein the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar” and wherein “the first end member removably attaches to the one end of the bar” and “mounting the bar of the stud in a fistula...” as recited in independent claims 21, 31, 36 and 37.

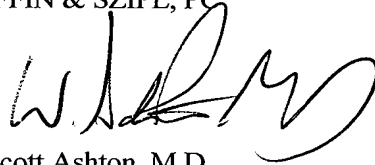
The Examiner has also failed to establish a proper motivation to justify the combination of the Denny Patent and the Edwards Patent because the subject matter of Edwards (i.e., conduit (30) and felt pad (50)), are not structures that a person of ordinary skill in the art would employ for intraoral use. In addition, the proposed combination of the Denny Patent and the Edwards Patent would obliterate the essential “ring” character of Denny’s device, and therefore cannot support a Section 103 rejection in accordance with McGinley v. Franklin Sports, Inc., 60 U.S.P.Q.2d 1001, 1110-11 (Fed. Cir. 2001).

For all of the above reasons, claims 21-31, 36 and 37 are in condition for allowance and a prompt notice of allowance is earnestly solicited.

Questions are welcomed by the below-signed Applicant.

Respectfully submitted,

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